K131770

FEB 2 6 2014

510(k) Summary

Date of Submission: Feb 25, 2014

Owner:

Name: Shenzhen ANT Hi-Tech Industrial Co., Ltd

Address: Jinhui Ave.18, Pingshan New District, Shenzhen, Guangdong, 518122, China.
No.46, Science and Technology Road, Yuquan Industrial Park,
Fenggang Town, Dongguan City, 523690 P.R. China

Submission Contact Person:

Name: Ms. Lynn. Fu

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Tel: 86-755-26903311 Fax: 86-755-26903355

Company: Shenzhen ANT Hi-Tech Industrial Co., Ltd

Address: Jinhui Ave.18, Pingshan New District, Shenzhen, Guangdong, 518122, China.

Proposed Device:

Trade name: Pressure Connecting Tube

Common name: High pressure tube, High Pressure Line, Pressure Connecting Line

Classification name: Diagnostic intravascular catheter (21CFR, 870.1200, Product Code DQO)

Classification:

Class: II

Product Code: DQO

Regulation Number: 870.1200

Predicate Device:

K 071196

Disposable High Pressure Injection Lines with and with out rotating adapters

Coeur, Inc

Intended Use:

The Pressure Connecting Tube is indicated for use during angiography procedures as a connecting line for the injection of liquid, such as radiopaque dye, saline, or other diagnostic fluids.

Device Description:

The Pressure Connecting Tube is a sterile, single use device which can withstand injection

pressures to 350~1200psi for use with power injectors to inject contrast media into implanted ports designed for use with power injectors.

This device is designed, like other legally marked devices, for one end to connect to the fluid source (such as an angiographic syringe) and the other end to connect to the catheter. The fluid such as radipoaque dye, saline, or other diagnostic fluid is then injected from the syringe, through the connecting tube, into the catheter. The contrast, saline, or other diagnostic fluid is then injected from the syringe through the High Pressure Tube, into the catheter.

According to the different pressure maintenance, the material of tube is PVC or PU, and the appearance is clear or braided.

Technological Characteristics

The design and technological characteristics of the Pressure Connecting Tube is substantially equivalent to the predicate devices except the following:
The predicate device pressure rating is 500 to 1200psi while the proposed device can withstand injection pressure form 350 to 1200psi.
The difference does not have a significant impact on the safety or effectiveness of the device.

Summary of Technological Characteristic compared to legally market device:

Characteristic	Proposed device	Legally market device (K071196)
Intended Use	This Pressure Connecting Tube is for use during angiography procedures as a connecting line for the injection of liquid, such as radiopaque dye, saline, or other diagnostic fluids.	The legally market device is for use during coronary angiography procedure as a connecting line for the injection of radiopaque dye, saline, or other diagnostic fluids.
Material	Plastic polymers	same
Flexible	YES	same
Connector Tube	Multiple lengths of braided or unbraided Clear or tinted	same
Components	With or without luer connector, luer lock connector. Protection cap.	Combinations of male and female luers (including rotating male luers), with and without dust caps(protection cap.
Packaging	Sealed Tyvek-lidded package.	same
Sterility	EtO	same
Disposable	YES	same
Pressure	350 to 1200psi	500 to 1200psi

Non-Clinical Testing Data:

The proposed device including three pressure sustaining types: 350psi, 600psi and 1200psi. The most complicated structure of each pressure type is selected to conduct the performance test. The results of the testing verified that the proposed device is capable of the intended use. The specific test items are listed below:

Summary of the non-Clinical Testing

Items	Reference Standards
Packaging	ISO 11607-1 Packaging for terminally sterilized medical devices —Part 1: Requirements for materials, sterile barrier systems and packaging systems
	• **Seal strength** ASTM F88 Standard Test Method for Seal Strength of Flexible Barrier Materials • **Integrity** ASTM F1929 Standard Test Method for Detecting Seal Leaks in Porous Medical Packaging by Dye Penetration • **Vacuum leak** ASTM D3078 Standard Test Method for Determination of Leaks in Flexible Packaging by Bubble Emission • **Accelerated aging** ASTM F1980-07 Standard Guide For Accelerated Aging Of Sterile Barrier Systems For Medical Devices. (Sterility)
Performance	ISO 594-1 Conical Fittings With A 6% (Luer) Taper For Syringes, Needles And Certain Other Medical Equipment - Part 1: General Requirements.
	ISO 594-2 Conical Fittings With A 6% (Luer) Taper For Syringes, Needles And Certain Other Medical Equipment - Part 2: Lock Fittings.
	Pressure Maintenance: Manufacturer's standard. The product should fulfill the requirements of pressure maintenance as claimed.
Sterilization	ISO 11135-1 Sterilization Of Health Care Products - Ethylene Oxide - Part 1: Requirements For Development, Validation And Routine Control Of A Sterilization Process For Medical Devices. • **EO/ECH Residuals** ISO 10993-7 Biological Evaluation Of Medical Devices - Part 7: Ethylene Oxide Sterilization Residuals. • **Bacterial Endotoxin** USP Chapter<85> Bacterial Endotoxins Test. • **Sterility** USP Chapter<71> Sterility Tests.

Biocompatibility of materials:
All the biocompatibilities of materials meet the requirements of ISO 10993 as listed below:

Summary of the Biocompatibility Testing

Items	Reference Standards
Cytotoxicity	ISO 10993-5 Biological Evaluation Of Medical Devices -- Part 5: Tests For In Vitro Cytotoxicity
Sensitization	ISO 10993-10 Biological Evaluation Of Medical Devices - Part 10: Tests For Irritation And Skin Sensitization.
Irritation	
System toxicity (acute)	ISO 10993-11 Biological Evaluation Of Medical Devices Part 11: Tests For Systemic Toxicity

Clinical Tests: NA.

Conclusion:
The predicate device has the same classification, intended use, technology designing and sterile specification. The differences between the proposed device and the predicated device will not affect the safety and efficiency.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

February 26, 2014

Shenzhen ANT Hi-Tech Industrial Co., Ltd
c/o Ms. Lynn Fu
Jinhui Ave. 18
Pingshan New District
Shenzhen. Guangdong. 518122
China

Re: K131770
Trade/Device Name: Pressure Connecting Tube
Regulation Number: 21 CFR 870.1200
Regulation Name: Diagnostic Intravascular Catheter
Regulatory Class: Class II
Product Code: DQO
Dated: January 5, 2014
Received: January 17, 2014

Dear Ms. Fu:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

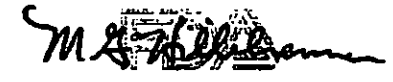
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indication for Use

510(k) Number: K131770

Device Name: Pressure Connecting Tube

Indications for Use:

The Pressure Connecting Tube is for use during angiography procedures as a connecting line for the injection of liquid, such as radiopaque dye, saline, or other diagnostic fluids.

Prescription Use √ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)